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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/530,693	07/03/2000	HANS PETER ZENNER	24218	3546

20529 7590 12/30/2005

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EXAMINER	
KOSAR, ANDREW D	
ART UNIT	**PAPER NUMBER**
1654	

DATE MAILED: 12/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/530,693	ZENNER ET AL.	
	Examiner	Art Unit	
	Andrew D. Kosar	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 September 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16,18 and 20-22* is/are pending in the application.

4a) Of the above claim(s) *7,8,10,11,18 and 20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,9,12-16,21 and 22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *8/25/00;8/11/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I and the species of claim 13 in the reply filed on September 28, 2005 is acknowledged. The traversal is on the ground(s) that Applicant asserts that it would not pose an undue burden to search Groups I and II together because the searches would likely overlap. Applicant's arguments have been considered, but have not been found persuasive. It is noted that the single species elected by Applicant is found in claim 13, not in claim 12, as identified in the Election (*see* page 8, 9/28/05).

Applicants assert that the restriction is improper under 35 USC § 121, citing various case law. The lack of unity requirement was properly set forth, where no rejection of the claims is made, but rather the Examiner identified that the 'technical feature' was not a contribution over the art. Further, it is noted that claim 19 has been cancelled (*see* claims 9/28/2005 page 5) and cannot be searched, as there is no subject matter recited in a cancelled claim.

With regards to the allegedly improper requirement for an election of species, Applicant is directed to 37 CFR § 1.146 (Election of Species), which states,

"In the first action on an application containing a generic claim to a generic invention (genus) and claims to more than one patentably distinct species embraced thereby, the examiner may require the applicant in the reply to that action to elect a species of his or her invention to which his or her claim will be restricted if no claim to the genus is found to be allowable. However, if such application contains claims directed to more than a reasonable number of species, the examiner may require restriction of the claims to not more than a reasonable number of species before taking further action in the application. [43 FR 20465, May 11, 1978; revised, 62 FR 53131, Oct. 10, 1997, effective Dec. 1, 1997]". In the instant case, claims 8, 11 and 13 recite patentably distinct species of the generic, and claim 12 is generic, as it describes a single subgenus of the invention- not a single species as asserted by Applicant. Claim 8 recites 'preferably' and thus does not describe a single species *per se*.

Applicant asserts the species elected reads upon claims 1-6, 9, 10, 12 and 14-18, however upon consideration of the claims, the Examiner has determined that the species of claim 13 reads upon claims 1-6, 9, 12-16, 21 and 22.

Claim 18 depends from a cancelled claim (*see* claims 9/28/2005 page 5), and, and thus cannot read upon the elected species.

Claims 7, 8, 10, 11, 18 and 20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention and/or species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on September 28, 2005.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-6, 9, 12-16, 21 and 22 have been examined on the merits.

Claims 7, 8, 10, 11, 18 and 20 have been included in the claim objections and rejections under 35 USC § 112 for Applicant's benefit only, and does not suggest or imply that the claims have been examined with respect to the prior art.

Information Disclosure Statement

References submitted but not in English have been considered insofar as the statement of relevance, English translation, and/or to the extent they are discussed in the specification. A6 (PTO-1449, 8/11/2005) have been considered in light of the English equivalent US Patent 5,994,350, furnished by the Examiner and relied upon in the rejection under 35 USC § 103(a).

Title

The title is objected to because vasopressin is misspelled 'vassopressin'.

Appropriate correction is required.

Claim Objections

Claims 3, 13, 18 and 20 are objected to for the following reasons:

Claim 3 recites, "the disturbance of illness of the inner ear", which should recite "the disturbance or illness of the inner ear", "with at least on of the symptoms", which should read "with at least one of the symptoms".

Claim 13 recites, "tert.-butyl" which should recite "tert-butyl", "methodybenzene" which should recite "methoxybenzene", and recites 'mixed' parentheses and bracket.

Claims 18 and 20 each depends from a cancelled claim, claims 17 and 19, respectively. Further, it is noted that a claim may only refer to more than one claim in the alternative (*see* 37 CFR 1.75(c), second sentence).

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8, 14-16, 18 and 20-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 8 recites "particularly", and it is unclear whether it is the only linear peptide of the claim, or whether it is merely exemplary of the subgenus 'linear peptides', and thus the claim is indefinite.

Claim 14 recites, "can be administered orally and intravenously", and it is unclear whether the compound is administered orally or intravenously or whether it must be

administered both orally and intravenously or whether it is merely optional that it need only be capable of being administered orally and intravenously, and thus the claim is indefinite.

Claim 15 recites " is used in a quantity", which is unclear as to how exactly the antagonist is "used". It is unclear whether the antagonist is 'used' to make a tablet, 'used' as a binder, or whether it is administered at a dose of 0.1 to 50 mg/kg /day, and thus the claim is indefinite

Claims 16, 21 and 22 recite "medicament intended for administration in a quantity of" 1 to 75, 5 to 50, and 5 to 25 wt.%, respectively, and it is unclear what the is weight %. Weight % is a relative term, requiring a benchmark for comparison, and it is unclear whether the wt.% is of the composition or of the patient, and thus the claims are indefinite.

Claims 18 and 20 depend from cancelled claims, and it is unclear as to what is being claimed, and therefore the claims are indefinite.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-6, 9, 12-16, 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over FOULON (WO 97/15556 A1, reference A6: PTO-1449, 8/11/2005), in view of SERRADEIL-LE GAL (reference A15: PTO-1449, 8/11/2005). In the interest of compact prosecution, US Patent 5,994,350, the US National Stage filing of WO 97/15556 A1, is relied upon as the English equivalent.

The instant claims are drawn to treating "disturbances or illnesses of an inner ear comprising administering at least one vasopressin receptor antagonist" to a patient in need. The elected species administered is known in the art as SR 121463A (e.g. page 2730, reference A15: PTO-1449, 8/11/2005).

Foulon teaches SR 121463A1 as the compound (claim 6, column 52, lines 59-61), as a pharmaceutical composition alone (claim 13) and in combination with irbesartan (claim 17, note Certificate of Correction sheet to amend the compound of claim 17), and a method "for the treatment of diseases in which the vasopressin and/or oxytocin receptor is involved which

comprises administering to a patient in need of such treatment an effective amount of a compound according to claim 6" (claim 23).

Foulon teaches that, "The compositions according to the invention can also be used in the treatment of ...Meniére's syndrome.." (column 24, lines 61-64) and that the pharmaceutical compositions of the present invention for various routes of administration, including oral or intravenous administration, "the active principles of formula (I) [the genus of the elected species], or their possible salts, solvates or hydrates can be administered as unit administration formulations, as a mixture with conventional pharmaceutical vehicles, to animals and to man" (column 23, lines 34-41). Additionally, "each unit dose can contain from 0.5 to 1000 mg, preferably from 1 to 500 mg, of active ingredients in combination with a pharmaceutical vehicle." (column 23, lines 54-56) and that, "In order to obtain the desired prophylactic or therapeutic effect, the dose of active principle can vary between 0.01 and 50 mg per kg of body weight per day." (column 23, lines 51-53).

It is noted that the instant specification states that Meniére's disease is "normally associated with the symptoms vertigo, impairment of hearing and tinnitus aurium" (page 4, specification). The art recognizes that the hearing impairment is low frequency hearing loss ("deep sound" as claimed) and that Meniére's disease is "linked" with endolymphatic hydrops.

Serradeil-Le Gal teaches SR 121463A, the elected species as the fumarate salt (e.g. page 2730, *Materials*).

The difference between that which is claimed, and that which is taught by Foulon, is that while Foulon teaches administering SR 121463A to treat diseases in which vasopressin receptor

is involved, and that Meniére's syndrome is one such disease, Foulon does not teach treating Meniére's disease with SR 121463A.

It would have been obvious to treat Meniére's disease with SR 121463A, and thus treat a disturbance or illness of the inner ear associated with vertigo, low frequency hearing impairment, tinnitus, and hydrops, as Foulon teaches that one could treat Meniére's disease by administration of the compounds of the invention, and SR 121463A is a claimed embodiment administered for treating a disease in which vasopressin receptor is involved.

One would have been motivated to administer SR 121463A to a patient in need to treat Meniére's disease, as Foulon teaches that one could administer any compound of the invention or the salts to treat any disease in which vasopressin receptor is involved.

One would have had a reasonable expectation for success in treating Meniére's disease with SR 121463A, as Foulon teaches that one could administer any compound of the invention or the salts, and provides guidance on the dosages to be administered and the routes of administration, to treat any disease in which vasopressin receptor is involved, including Meniére's disease.

With regards to the concentrations of the active element in the formulation administered (claims 16, 21 and 22), it would have been obvious to one skilled in the art at the time of invention to determine all optimum and operable conditions (e.g. concentration of the active ingredient in the formulation/medicament), because such conditions are art-recognized result-effective variables that are routinely determined and optimized in the art through routine experimentation, as Foulon teaches the dosages that can be formulated, *supra*. ("[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the

optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). *See* MPEP § 2145.05).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

NO CLAIMS ARE ALLOWED.

The prior art made of record on the attached PTO-892 and not relied upon in any rejection is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew D. Kosar whose telephone number is (571)272-0913. The examiner can normally be reached on Monday - Friday 8am-430pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571)272-0974. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Art Unit 1654

ANISH GUPTA
PRIMARY EXAMINER